K012487
p1/2

FEB 21 2002

510(k) Summary

SphygmoCor™ Px

Common/Classification Name: Blood Pressure Computer as classified per 21 CFR 870.1110

AtCor Medical Pty Ltd.
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West Ryde
NSW 2114 Australia

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Contact: Ross Harricks, CEO

A. Legally Marketed Predicate Devices

The SphygmoCor SCOR-Px is substantially equivalent to the SphygmoCor Mx cleared under K002742. Both systems have the same intended use, which is to provide the calibrated central aortic pressure waveform.

B. Device Description

The SphygmoCor SCOR-Px is a computerized tool for the assessment of blood pressure. The SphygmoCor can calculate the calibrated ascending aortic pressure waveform using the radial artery pressure waveform recorded non-invasively from a radial artery tonometer and a brachial cuff measurement.

An eight-second segment of the radial artery pressure signal is processed in the SphygmoCor electronics module to derive the calibrated ascending aorta pressure waveform and to derive central pressure waveform parameters.

The signal processing electronics module is attached to a PC computer through a serial RS-232C port.

The patient's study report appears on the PC computer and displays the measured (radial) and calculated (central) waveforms, allows input of patient information, and provides the operator with instructions. It uses an IBM-compatible computer (notebook or desktop) to run the SphygmoCor computer software suite.

C. Indications for Use

The SphygmoCor Px is indicated for use in those patients where information related to the ascending aortic pressure is desired, but in the opinion of the physician, the risks of the intra-arterial radial artery pressure recording procedure may outweigh the benefits of using the SphygmoCor Mx system with an invasive radial pressure input.

D. Substantial Equivalence Summary

The primary function of both types of devices is to provide the calibrated central aortic blood pressure waveform. The SphygmoCor Mx requires the pressure catheter to be placed directly in the radial artery to acquire the radial artery pressure waveform and, simultaneously, pressure measurements. The SphygmoCor Px uses the signal from a non-invasive tonometer placed over the radial artery to obtain the waveform, with the systolic and diastolic pressure calibrations being obtained from a conventional brachial cuff measurement. The SphygmoCor Px derives from this calibrated radial artery waveform the central aortic blood pressure waveform and a range of central arterial indices of ventricular-vascular interaction.

Since the SphygmoCor Mx and Px use the same input signal processing software, differences in the calculated central aortic blood pressure waveforms would only be due to differences in the patient characteristics. A study was carried by Kelly et al. out that compared the radial artery pressure waveforms measured invasively with a catheter in the radial artery to radial artery pressure waveforms produced by the non-invasive Millar tonometer calibrated with a brachial cuff measurement. This Kelly study demonstrated that the two sets of input radial artery waveforms are substantially equivalent. Other publications, and the experience of the clearance of the Colin 7000 and the Millar tonometer itself, additionally support substantial equivalence of the SphygmoCor Px to the predicate.

E. Technological Characteristics

See Device Description, above.

F. Performance Testing

The entire system has been tested to demonstrate compliance with IEC-601-1 (including its subparagraphs) Electro-Medical Equipment Safety Standard. Testing was done to demonstrate compliance with this standard for input voltages of both 110 and 220 volts. The biocompatibility testing clause of the standard was not applied since the only patient contact material is in the previously cleared tonometer. This testing demonstrates that the SphygmoCor Px meets electrical and environmental safety standards for safe use.

G. Conclusions

AtCor Medical has demonstrated through its comparison of performance with the predicate device that the SphygmoCor Px is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2002

AtCor Medical Pty. Ltd.
c/o Jur Strobos, M.D.
Olsson, Frank & Weeda, P.C.
1400 16th Street, NW
Suite 400
Washington, DC 20036

Re: K012487
Trade Name: SphygmoCor Px
Regulation Number: 21 CFR 870.1110
Regulation Name: Blood Pressure Computer
Regulatory Class: II (two)
Product Code: DSK
Dated: November 28, 2001
Received: November 28, 2001

Dear Dr. Strobos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

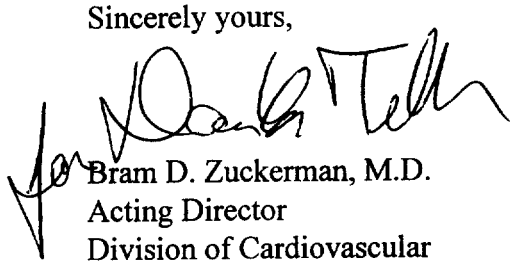
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012487

Device Name: SphygmoCor Px

Indications for Use:

The SphygmoCor Px provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. The SphygmoCor is used with a tonometer over the radial artery calibrated with a standard cuff blood pressure measurement. It is to be used in those patients where information related to the ascending aortic pressure is desired but in the opinion of the physician, the risks of the cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012487